

State of Wisconsin Governor Scott Walker

Department of Agriculture, Trade and Consumer Protection

Ben Brancel, Secretary

DATE: January 23, 2015

TO: The Honorable Mary Lazich President, Wisconsin State Senate Room 220 South, State Capitol PO Box 7882 Madison, Wisconsin 53707

> The Honorable Robin Vos Speaker, Wisconsin State Assembly Room 211 West, State Capitol P.O. Box 8953 Madison, WI 53708

FROM: Ben Brancel, Secretary Steve Ingham, Division of Food Safety Administrator

SUBJECT: ATCP 55-Meat and Meat Food Products; Final Draft

The Department of Agriculture, Trade and Consumer Protection (DATCP) is transmitting this rule for legislative committee review, as provided in s. 227.19 (2) and (3), Stats. DATCP will publish notice of this referral in the Wisconsin Administrative Register, as provided in s. 227.19(2), Stats. Chapter ATCP 55 (Meat and Meat Food Products) regulates Wisconsin's state-inspected meat program. The proposed rule specifies corrective actions that must be imposed by state-licensed meat establishments on certain livestock producers who, on two or more occasions during the past year, submitted animals for slaughter which tested positive for illegal drug residues. The corrective actions must be completed by the producer before the establishment operator accepts animals from the producer for slaughter.

Background

Medications are important for maintaining healthy livestock. However, if medications are not carefully managed, illegal drug residues may remain in animals submitted for slaughter. Residues of medications in meat, particularly antibiotics and anti-inflammatory agents, can pose a direct health risk to people who consume the meat. For example, some people may have an allergic reaction if exposed to penicillin. The anti-inflammatory drug flunixin may cause gastrointestinal and kidney problems. Drug residues may disrupt normal meat fermentation processes, such as those needed to make summer sausage, and increase the risk that disease-causing bacteria will grow during processing.

Meat establishment operators are expected by the United States Department of Agriculture - Food Safety and Inspection Service (USDA-FSIS) to check the published Residue Repeat Violators List. The list identifies livestock producers whose animals have yielded carcasses which had positive tissue drug residue test results at two or more times in the past year. Meat establishment operators are also expected to take appropriate January 23, 2015 The Honorable Mary Lazich The Honorable Robin Vos Page 2 of 4

measures before accepting animals from these producers. Recent federal data suggest that dairy cattle are responsible for a high proportion of repeat tissue drug residue offenses. As a leading producer of dairy cattle, the reputation of Wisconsin's agriculture is jeopardized by the few Wisconsin producers who repeatedly violate prohibitions against drug residues in livestock and meat products.

Rule Content

Currently ATCP 55 (Meat and meat food products) addresses the production of meat and meat food products starting with the submission of an animal for slaughter for human consumption and, by reference, adopts USDA regulations prohibiting the slaughter of "downer" (non-ambulatory) cattle for human food or feed destined for bovine animals.

Current rules prohibit slaughter of a food animal for human consumption or submission of a food animal for slaughter if the person knows or has reason to know the animal is diseased or injured. The rule will further prohibit someone from slaughtering, or submitting for slaughter, a food animal for human consumption if they know that the animal will yield an adulterated carcass. The rule adopts the definition for adulterated, as applied to a carcass, which is already contained in federal regulations pertaining to slaughter operations. According to this definition, a carcass containing violative drug residues is considered adulterated. The rule then clarifies that the slaughter of animals from producers included on the USDA Residue Repeat Violator List for Use by Livestock Markets and Establishments is not prohibited if the producer provides written evidence that they have completed a course on proper administration of animal medications. The department will approve a course or courses which are acceptable. Completion of the approved course(s) will require the involvement of the livestock producer's veterinarian.

The rule also revises a requirement for a person who knows or has reason to know that he or she is submitting a diseased or injured animal for slaughter to sign and deliver a written statement to the person who will perform the slaughter. The proposed rule will revise the requirement that the written statement include a list of all drugs administered to the animal as treatments or feed within 30 days prior to the slaughter submission date. The rule will instead require that the statement certify that the date of delivery, the delivery method, and the withdrawal time following delivery of all drugs provided to the animal as treatments or feed additives have complied with a veterinarian's prescription or the manufacturer's recommendations (over-the-counter drugs). This revision acknowledges that some drugs may require a withdrawal time longer than 30 days and that withdrawal time may vary according to the method by which the drug is delivered to the animal.

Summary of, and Comparison with Existing or Proposed Federal Statutes and Regulations

Federal meat and poultry inspection regulations require meat and poultry processors to adopt Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is an approach for preventing food safety hazards that involves identifying key food processing steps essential for ensuring safety. Establishment operators must develop a plan to monitor and document that each key step is functioning properly and minimizing the risk associated with food safety hazards. As part of their HACCP plan, federally- and state-inspected establishments are required by 9 CFR 417.2 (a) (3) (v) to identify preventive measures for food safety hazards that could arise from drug residues.

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One approach for minimizing drug residue risks is for abattoir operators to avoid accepting animals from sources that have had drug residue violations in the past. Since past performance is a potential indicator of whether an animal may have a drug residue problem, federal establishment operators are expected, but not required, to consult the federal Residue Repeat Violator List for Use by Livestock Markets and Establishments before accepting animals for slaughter. This list is compiled as part of the National Residue Program at USDA-FSIS, which has collected data on drug residues in meat, poultry and egg products since 1967. Producers who are found to have had more than one residue violation in the previous 12 months under this sampling program are placed on the federal Residue Repeat Violator List.

State meat inspection programs operate under a cooperative agreement with the USDA-FSIS. Under this agreement, state meat inspection programs are required to adopt regulations that are "at least equal to" federal meat and poultry inspection regulations. In addition, Wisconsin is one of three states recently accepted into the Cooperative Interstate Shipment (CIS) program allowing certain selected meat establishments to ship their products in interstate commerce. States in the CIS program must adopt regulations that are the "same as" federal meat inspection regulations.

The proposed rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations for minimizing the risk of drug residue violations at state-inspected meat plants. It will enhance the effectiveness of oversight by requiring an abattoir operator to enforce an educational corrective action which would be completed by the producer well before federal regulatory action is needed.

Comparison with Rules in Adjacent States

Michigan currently does not operate a state meat and poultry inspection program; all meat processed in Michigan for wholesale is federally-inspected by USDA. Illinois' state meat inspection program includes USDA's Federal-State Cooperative program (formerly known as the "Talmadge-Aiken" program). Under this program, state inspectors conduct federal inspections. Minnesota and Iowa operate state meat inspection programs or the USDA program, are expected to minimize the risk associated with drug residues and to consult the USDA's Residue Repeat Violator List for Use by Livestock Markets and Establishments before accepting animals for slaughter. The approach proposed in this rule revision is innovative and goes beyond requirements in neighboring states which operate state meat inspection programs. Although enforcement of the provisions in the proposed rule is expected to be infrequent, the provisions are necessary to protect consumer trust in meat from Wisconsin-inspected establishments.

Effect on Small Business

This rule change is anticipated to have very little impact on meat establishment operators, who will be required to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List and, if a producer is on the list, determine whether the mandatory corrective action has been taken. Since very few livestock producers from Wisconsin and neighboring states are on this list, the proposed rule change will have no impact on the vast majority of livestock producers who follow existing regulations and have a strong working relationship with their veterinarians. There will be a slight short-term negative economic impact on livestock producers who must attend a course and improve documentation of animal medications as a

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result of the proposed rule. There will be a slight impact on the veterinarians of these few producers, because completion of the course will require involvement of the veterinarian. To the extent that the proposed rule prevents drug residue problems and condemnation of carcasses, there will be a positive long-term economic impact. The rule will not modify fees or have an economic impact on local governmental units or public utility rate payers.

Small Business Regulatory Review Report

The Small Business Regulatory Review Board did not issue a report on this rule.

Public Hearings

DATCP held three hearings at the following locations:

April 22, 2014	Madison, Wisconsin
April 23, 2014	Eau Claire, Wisconsin
April 25, 2014	Green Bay, Wisconsin

Following the public hearing, the hearing record remained open until May 9, 2014 for additional written comments. One person representing the Cooperative Network attended the hearings. The Cooperative Network did not take a position on the proposal. We received written comments from the Wisconsin Veterinary Medical Association expressing support for the rule and suggesting language changes to clarify rule requirements.

Changes from the Hearing Draft

We made all of the changes suggested by the Legislative Council Rules Clearinghouse. Both the Legislative Council Rules Clearinghouse and the Wisconsin Veterinary Medical Association (WVMA) suggested revisions to the language defining adulteration. In response to the WVMA comments we added, by reference, the USDA definition of "adulterated" and separated the prohibition against presenting adulterated animals for slaughter and the corrective action required for producers who are on the USDA Residue Repeat Violators List. Subsequent to the July 23, 2014 Board meeting, the rule text has been clarified to indicate that the prohibition is against presentation of an animal which will yield an adulterated carcass. We also broadened the list of information required from the producer when he/she presents a diseased or injured animal for slaughter. The additional language reflects the complexity of FDA requirements for drug withdrawal times before slaughter. In response to a suggestion from the WVMA that the course required as a corrective action after repeat drug residue violations be completed within 180 days of the producer's name appearing on the list, we modified the language to require that the course be started within 30 days after the producer's name appeared on the list, and be completed within 180 days after being started. We also adopted a WVMA suggestion to require that all drugs used to treat a diseased or injured animal presented for slaughter be certified either as administered as prescribed by a licensed veterinarian or as recommended on the manufacturer's label (for over-the-counter medications).